

### **REMARKS**

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

#### **I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 1-8 are currently under consideration. Claims 1, 5, and 7 are amended, and claim 6 is canceled without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that the claims herewith are patentably distinct over the prior art, and these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims presented herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply to clarify the scope of protection to which Applicant is entitled.

Support for the amended claims can be found throughout the specification and claims as originally filed. In particular, support for amended claim 1 can be found, for example, on page 6, line 10 - page 8, line 8, and in Examples 1, 3, and 4. Support for amended claim 5 can be found, for instance, on page 9, lines 6-21, on page 7, line 11 - page 8, line 8, in Example 5, and in claim 6 as originally filed.

#### **II. THE REJECTION UNDER 35 U.S.C. § 112, 2<sup>ND</sup> PARAGRAPH IS OVERCOME**

Claims 1-8 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. This rejection is respectfully traversed.

Specifically, the Office Action contends that claim 1 recites the limitations “primary active constituents,” “secondary active constituents,” and “final active constituents,” which are considered vague since it is unclear to which activity the term “active” refers. In response, claim 1 is amended to remove the recitation of these terms from the claim language, thereby obviating the rejection.

Accordingly, reconsideration and withdrawal of the rejection under § 112, second paragraph are respectfully requested.

### **III. THE REJECTION UNDER 35 U.S.C. § 102(b) IS OVERCOME**

Claims 5, 6, and 8 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Machida et al. (Chem Pharm Bull 50: 1041-1044, 2002; hereinafter “Machida”). The Office Action asserts that Machida relates to the isolation of loganin and sweroside as active constituents from *Lonicera japonica* Thunb. The rejection is respectfully traversed.

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

With this in consideration, Applicants assert that Machida does not anticipate the invention of claim 5, which is amended herein to clarify that the disclosed drug is comprised of “sweroside and loganin as effective active ingredients, wherein the drug is administered alone or with a pharmaceutically acceptable carrier.” In particular, Machida does not teach or suggest that sweroside and loganin can be effective active ingredients in an anti-inflammatory and analgesic drug; instead, Machida only mentions sweroside and loganin as components of one of four iridoid glycosides from the stems and leaves of *L. japonica*. There is no teaching or suggestion that sweroside and loganin, in particular, can be used as active ingredients in a drug. Similarly, Machida does not contain an enabling disclosure that could allow a person skilled in the art to recognize that sweroside and loganin can be used as active ingredients in an anti-inflammatory and analgesic drug.

In addition, Machida does not teach or suggest that the drug is administered alone or with a pharmaceutically acceptable carrier, as disclosed in claim 5. In fact, there is no mention in Machida regarding how the drug can be administered.

Therefore, it is asserted that Machida does not anticipate claim 5, as well dependent claim 8. Accordingly, reconsideration and withdrawal of the rejection under § 102(b) are respectfully requested.

#### IV. REJECTIONS UNDER 35 U.S.C. §103(a) ARE OVERCOME

Claims 5-8 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Machida. According to the Office Action, there are only slight differences between the loganin and sweroside mentioned in Machida and the active constituents of the claimed invention. Further, the Office Action alleges that the amount of active constituents provided in the claimed invention is allegedly a matter of judicious selection and a skilled artisan would be able to determine the proper amounts. The rejection is respectfully traversed.

Before discussing the rejection, it is thought proper to briefly state what is required to sustain such a rejection. The issue under §103 is whether the PTO has stated a case of *prima facie* obviousness. "The PTO has the burden under §103 to establish a *prima facie* case of obviousness." In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). To satisfy this burden, the PTO must meet the criteria set out in M.P.E.P. §706.02(j):

...three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

Moreover, the obviousness analysis must comply with the statutory scheme as explained by the Supreme Court in Graham v. John Deere Co., 383 U.S. 1, 17 (1966), namely, consideration must be given to: (1) the scope and content of the prior art, (2) the differences between the prior art and the claimed invention, (3) the level of ordinary skill in the pertinent art, and (4) additional evidence, which may serve as indicia of non-obviousness.

With the above background in mind, Applicants assert that the Patent Office has failed to meet its burden of making a *prima facie* case of obviousness, as it has failed to show that the

cited reference discloses each and every element of the claimed invention and that there is a reasonable expectation of success.

Firstly, as noted above, Machida does not teach or suggest all of the limitations of instant claim 5. For example, Machida does not teach or suggest an anti-inflammatory drug comprising sweroside and loganin as active ingredients. Machida relates to four isolated iridoid glycosides, wherein one of the glycosides showed two signals through <sup>1</sup>H-NMR spectrum analysis that were similar to loganin and sweroside. However, there is no teaching that loganin and sweroside can be used as effective active ingredients in an anti-inflammatory and analgesic drug. In addition, Machida does not teach or suggest that the drug is administered alone or with a pharmaceutically acceptable carrier as disclosed in claim 5. Hence, Machida does teach or suggest each and every element of claim 5 or dependent claims 7 and 8.

Furthermore, one skilled in the art would not reasonably expect to successfully arrive at the present invention based on the Machida reference. To reiterate, Machida relates to four isolated iridoid glycosides, wherein one of the glycosides may be comprised of loganin and sweroside. However, there is no teaching or suggestion in Machida that loganin and sweroside, specifically, can have anti-inflammatory and analgesic effects. Loganin and sweroside are only two of many components found in *L. japonica*, and Machida does not distinguish loganin and sweroside as the source of therapeutic effects. In contrast, the present invention has identified loganin and sweroside apart from other ingredients as having anti-inflammatory and analgesic effects. Hence, a skilled artisan would not learn from Machida that loganin and sweroside can be used as effective active ingredients in an anti-inflammatory and analgesic drug.

Clearly, Machida does not anticipate the invention disclosed in claim 5, or the inventions of dependent claims 7 and 8. Accordingly, reconsideration and withdrawal of the rejection under § 103(a) are respectfully requested.

**CONCLUSION**

In view of the remarks and amendments herewith, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By:

A handwritten signature in black ink, appearing to read 'Ronald S. Santucci', is written over a horizontal line.

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